

Food and Drug Administration

Chicago District 550 West Jackson Blvd., 15th Floor Chicago, Illinois 60661 Telephone: 312-353-5863

October 21, 2004

WARNING LETTER CHI-2-05

<u>CERTIFIED MAIL</u> <u>RETURN RECEIPT REQUESTED</u>

Mr. Elwood E. Richard, President Now Natural Foods, Inc. 395 S. Glen Ellyn Road Bloomingdale, IL 60108

Dear Mr. Richard:

On June 25, 2004, an investigator from the Food and Drug Administration (FDA) collected a sample of Ginseng from your plant labeled: "NOW American Ginseng 5% Ginsenosides 500 mg**capsules*** Manufactured by NOW FOODS, BLOOMINGDALE, IL 60108*** LOT# 596409***BEST BY 06/07***". The sample was analyzed by our laboratory and found to contain the pesticides quintozene, pentachloroaniline, and oxadixyl. The Report of Sample Analysis is attached for your information.

The article is adulterated within the meaning of 21 U.S.C 342(a)(2)(B) while held for sale after shipment in interstate commerce in that it bears and contains pesticide chemical residues, namely quintozene, pentachloroaniline, and oxadixyl, which are unsafe within the meaning of 21 U.S.C. 346(a) because no tolerances or exemptions from tolerances have been granted for the use of these pesticide chemicals on ginseng.

As a manufacturer of food, within the meaning of 21 U.S.C. 321(ff), you are responsible for assuring that the products you distribute are not adulterated and are otherwise in compliance with the law. Failure to do so may result in regulatory action, without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct these violations and preclude their recurrence. Your firm's letters to this office of August 16 and 17, 2004, indicate you have taken steps for removal of Lot # 596409 of your ginseng product from the market. Please include any further steps that you have or will take in the future to prevent the recurrence of the violations in other lots of ginseng product. Please include copies of any available documentation demonstrating that corrections have been made.

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Your reply should be sent to the attention of Paul Boehmer, Compliance Officer, at the Chicago District office shown on this letterhead.

Sincerely,

Scott J. MacIntire
District Director

Enclosure: Report of Sample Analysis